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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Antonio Covacci, et al.

Application No.: 10/615,668

Filing Date: July 8, 2003

For: *Helicobacter Pylori* CAI Antigen

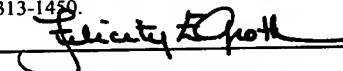
Confirmation No.:

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: October 6, 2003

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TYPED NAME: Felicity E. Groth
REGISTRATION NO.: 47,042

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

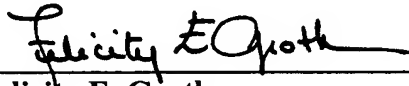
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
 - ☒ Copies of references **1 thru 60** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/410,835**, filed **October 1, 1999**.

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There are no listed references which are not in the English language.

Date: October 6, 2003

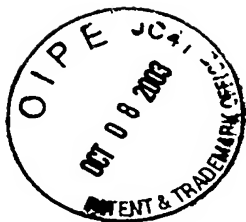


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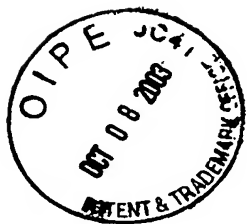


Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. CHIR-0337	Application No. 10/615,668
		Applicant Antonio Covacci, et al.	
		Filing Date July 8, 2003	Group Not Yet Assigned
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	1	Austin et al., "Structural Comparison of Urease and a GroEL Analog from <i>Helicobacter pylori</i> ", <i>J. Bacteriol.</i> , 1992 , 174(22), 7470-7473	
	2	Apel et al., "Antibody Response of Patients Against a 120 kDa Surface Protein of <i>Campylobacter pylori</i> ", <i>Aentralblat fur Bakterio. Microb. Und Hygiene</i> , 1988 , 268, 271-276	
	3	Blaser, "Gastric <i>Campylobacter</i> -like Organisms, Gastritis, and Peptic Ulcer Disease", <i>Gastroenterology</i> , 1987 , 93, 371-383	
	4	Blaser, " <i>Helicobacter pylori</i> : Its Role in Disease", <i>Clin. Infect. Dis.</i> , 1992 , 15, 386-391	
	5	Blaser, M., "H.pylori associated disease involves host and bacterial factors," <i>HP World-Wide</i> , February 1992 , 1-8	
	6	Clayton, C.L. et al., "Molecular Cloning and Expression of <i>Campylobacter pylori</i> Species-Specific Antigens in <i>Escherichia coli</i> K-12," <i>Infection Immunity</i> , 1989 , 57(2), 623-629	
	7	Cover et al., "Characterization of and Human Serologic Response to Proteins in <i>Helicobacter pylori</i> Broth Culture Supernatants with Vacuolizing Cytotoxin Activity", <i>Infect. Immun.</i> , 1990 , 58(3), 603-610	
	8	Cover et al., "Purification and Characterization of the Vacuolating Toxin from <i>Helicobacter pylori</i> ", <i>J. Biol. Chem.</i> , 1992 , 267(15), 10570-10575	
	9	Cover et al., "Serum Neutralizing Antibody Response to the Vacuolating Cytotoxin of <i>Helicobacter pylori</i> ", <i>J. Clin. Invest.</i> , 1992 , 90, 913-918	
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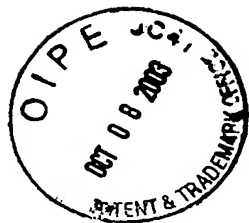


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	11	Crabtree et al., "Expression of 120 kilodalton protein and cytotoxicity in <i>Helicobacter pylori</i> ", <i>J. Clin. Pathol.</i> , 1992 , 45, 733-734	
	12	Cussac et al., "Expression of <i>Helicobacter pylori</i> Urease Genes in <i>Escherichia coli</i> Grown under Nitrogen-Limiting Conditions", <i>J. Bacteriol.</i> , 1992 , 174(8), 2466-2473	
	13	Dooley et al., "Prevalence of <i>Helicobacter Pylori</i> Infection and Histologic Gastritis in Asymptomatic Persons", <i>New Engl. J. Med.</i> , 1989 , 321, 1562-1566	
	14	Drumm et al., "Intrafamilial Clustering of <i>Helicobacter Pylori</i> Infection", <i>New Engl. J. Med.</i> , 1990 , 322(6), 359-363	
	15	Dunn et al., "Identification and Purification of a cpn60 Heat Shock Protein Homolog from <i>Helicobacter pylori</i> ", <i>Infect. Immun.</i> , 1992 , 60(5), 1946-1951	
	16	Evans et al., "Urease-Associated Heat Shock Protein of <i>Helicobacter pylori</i> ", <i>Infect. Immun.</i> , 1992 , 60(5), 2125-2127	
	17	Evans et al., "A Sensitive and Specific Serologic Test for Detection of <i>Campylobacter pylori</i> Infection", <i>Gastroenterology</i> , 1989 , 96, 1004-1008	
*	18	Figura et al., <i>H. Pylori, Gastritis and Peptic Ulcer</i> , Malfrthheiner et al. (eds.), Springer Verlag, Berlin, 1990	
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	20	Goodwin et al., "Transfer of <i>Campylobacter pylori</i> and <i>Campylobacter mustelae</i> to <i>Helicobacter</i> gen. nov. As <i>Helicobacter pylori</i> comb. Nov. And <i>Helicobacter mustelae</i> comb. Nov., Respectively," <i>Int. J. Syst. Bacteriol.</i> , 1989 , 39(4), 397-405	
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**A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous to send and easily obtainable by the Examiner.



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	21	Graham et al., "Seroepidemiology of <i>Helicobacter pylori</i> Infection in India: Comparison of Developing and Developed Countries", <i>Digestive Diseases and Sciences</i> , 1991 , 36(8), 1084-1088	
	22	Jones et al., "Antibody to the gastric campylobacter-like organism (" <i>Campylobacter pyloridis</i> ") — Clinical correlations and distribution in the normal population", <i>Med. Microbiol.</i> , 1986 , 22, 57-62	
	23	Kahn, S. et al., "The major 85-KD surface antigen of the mammalian form of <i>Trypanosoma cruzi</i> is encoded by a large heterogeneous family of simultaneously expressed genes," <i>J. Exp. Med.</i> , 1990 , 172(2), 589-597	
	24	Leunk, "Production of a Cytotoxin by <i>Helicobacter Pylori</i> ", <i>Rev. Infect. Dis.</i> , 1991 , 13(8), S686-S689	
	25	Leying et al., "Cloning and genetic characterization of a <i>Helicobacter pylori</i> flagellin gene", <i>Mol. Microbiol.</i> , 1992 , 6(19), 2863-2874	
	26	Morris et al., "Seroepidemiology of <i>Campylobacter pyloridis</i> ", <i>N.Z. Med. J.</i> , 1986 , 99(809), 657-659	
	27	Orkin, S.H. et al., Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy, December 1995 , 41 pages	
	28	Parsonnet et al., " <i>Helicobacter Pylori</i> Infection and the Risk of Gastric Carcinoma", <i>New Engl. J. Med.</i> , 1991 , 325(16), 1127-1131	
	29	Pei, Z. et al., "Identification Purification and Characterization of Major Antigenic Proteins of <i>Campylobacter-Jejuni</i> ," <i>J. Biol. Chem.</i> , 1991 , 266(25), 16363-16369	
	30	Perez-Perez et al., "Characteristics of <i>Helicobacter pylori</i> Variants Selected for Urease Deficiency", <i>J. Infect. Immun.</i> , 1992 , 60(9), 3658-3663	
	31	Thomas et al., "Isolation of <i>Helicobacter pylori</i> from human faeces", <i>Lancet</i> , 1992 , 340, 1194-1195	
	32	Warren et al., "Unidentified Curved Bacilli on Gastric Epithelium in Active Chronic Gastritis", <i>Lancet</i> , 1983 , 1273-1275	
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33	Figura, N. et al., "Serum Antibodies to the Vacuolating Toxin Produced by <i>Helicobacter Pylori</i> ; <i>Gastritis and Peptic Ulcer</i> , P. Malfertheiner, et al.(Eds.), Springer-Verlag, Berlin, 1990 , 159-161	
34	Covacci, A. et al., "Molecular characterization of the 128-kDa immunodominant antigen of <i>Helicobacter pylori</i> associated with cytotoxicity and duodenal ulcer", <i>Proc. Natl. Acad. Sci. USA</i> , 1993 , 90, 5791-5795	
35	Tummuru, M.K.R. et al., "Cloning and Expression of a High-Molecular-Mass Major Antigen of <i>Helicobacter pylori</i> : Evidence of Linkage to Cytotoxin Production", <i>Infection and Immunity</i> , 1993 , 61(5), 1799-1809	
36	Clayton, et al., in: " <i>Helicobacter pylori</i> , Gastritis and Peptic Ulcer," Malfertheiner, et al. (Eds.), <i>Spring-Verlag, Berlin</i> , 1990 , 167-171	
37	Crabtree, et al., "Mucosal Humoral Immune Response to <i>Helicobacter Pylori</i> in Patients with Duodenitis", <i>Dig. Dis. Sci.</i> , 1991 , 36, 1266-1273	
38	Crabtree, et al., "Mucosal IgA Recognition of <i>Helicobacter Pylori</i> 120 kDa Protein, Peptic Ulceration, and Gastric Pathology", <i>Lancet</i> , 1991 , 338, 332-335	
39	Gerken, et al., sequence submitted to EST-STS by Utah Center for Humans Genome Res. University of Utah, 1993 , Accession No. L18544	
40	Hirschl, et al., in: " <i>Helicobacter pylori</i> , Gastritis and Peptic Ulcer," Malfertheiner, et al. (Eds.), <i>Spring-Verlag, Berlin</i> , 1990 , 141-146	
41	Hammermeister, et al., "Elevated Risk of <i>Helicobacter Pylori</i> Infection in Submarine Crews", <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , 1992 , 11(1), 9-14	
42	Tummuru, et al., in: Abstracts of the 91 st General Meeting of the American Society for Microbiology, Dallas, TX, May 5-9, 1991 (abstract B-127)	
43	Nakajima, et al., <i>J.Cell. Biol.</i> , 1991 , 113, 245-260	
44	Graham, et al., "Epidemiology of <i>Helicobacter Pylori</i> in an Asymptomatic Population in the United States", <i>Gastroenterology</i> , 1991 , 100, 1495-1501	
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	45	4,882,271	11/21/89	Evans et al.	435	7
	46	5,292,658	03/08/94	Cormier, et al.	435	252.33
	47	5,354,854	10/11/94	Bourque, et al.	536	23.1
	48	5,403,924	04/04/95	Cover et al.	536	23.1
	49	5,721,349	02/24/98	Cover, et al.	536	22.1
	50	5,733,740	03/31/98	Cover, et al.	435	7.32
	51	5,876,943	03/02/99	Cover, et al.	435	6
	52	6,090,611	07/18/00	Covacci, et al.	435	252.3
	53	6,153,390	11/28/00	Cover, et al.	435	6

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	54	EP 0329570 A2	08/23/89	EP	X	
	55	EP 0367644 A1	05/09/90	EP	X (Abstract)	
	56	WO 87/05943	10/08/87	PCT		
	57	WO 89/08843	09/21/89	PCT	X	
	58	WO 91/09049	06/27/91	PCT	X	
	59	WO 90/04030	04/19/90	PCT	X (Abstract)	
	60	WO 90/06696	06/28/90	PCT		

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